

Changes to an Approved Application Administrative Handling and Review of Annual Reports

SOPP 8411.1

Appendix 2

Boilerplate Letter: Inappropriate Use of Annual Report

USE: As a result of the final rule, “Changes to an Approved Application” published in the Federal Register on July 24, 1997, applicants may submit certain changes to their license application in an Annual Report. When a applicant inappropriately submits a change requiring submission as a supplement, in a annual report, the applicant must be notified immediately that CBER does not agree with the classification and that the change must be reported in a supplement.

Name of Authorized Official
Company Name
Address

Dear __ (Authorized Official) __:

We have received your annual report to your (product/biologics) license for product name to include (brief summary) submitted on (date).

We disagree with your assessment that [item] is appropriate for submission in an Annual Report. This change(s) in (manufacturing methods, your facility, your labeling) should be reported in a supplement (requiring prior approval/ changes being effected/ changes being effected in 30 days). You are advised to submit a supplement to document this change and [do what with current operations/distributed product].

All future correspondence, supportive data, or labeling related to this supplement application should be submitted in triplicate and should be addressed to the Director, Center for Biologics Evaluation and Research, HFM-99, HHS/PHS, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448.

If you have any additional question, please call (name) at (phone).

Sincerely yours,

Division Signatory Authority